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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Robert Collette
V.P. of Science and Technology
1901 North Fort Myer Drive, Suite 700
Arlington, VA 22209

Dear Mr. Collette:

The Office of Regulatory Affairs supports the efforts of your members to assess seafood manufacturers and suppliers for product quality before attempting export to the US. We share your position that the responsibility for seafood product quality and safety resides first at the manufacturer. The FDA objective of our current testing initiative for chloramphenicol (CAP) in imported food is the identification of any detectable residues to prevent adulterated product from US markets. We encourage you to continue working with seafood producers to eliminate CAP as a source of drug residue by the manufacturer. We will continue to detain any imported product when residues are detected and act immediately on information regarding suspect product. I have attempted to address the major concerns expressed in your January 8, 2003 correspondence.

Regarding the level of CAP residues that initiate FDA action, please note that there has been no change in FDA policy regarding the presence of CAP in food. Because of our public health concerns, no residues of CAP are permitted at any level. The zero tolerance policy has been widely communicated to state, foreign regulatory agencies, the domestic and import seafood industries and the general public. ORA will respond immediately to findings of CAP at any level consistent with this policy and our public health mission.

The practical regulatory limit for the control of CAP in food is based on the analytical limit of detection. The limit of detection established for any product will be the lowest level of CAP that meets the data quality standards for confirmation of identity. FDA's regulatory test limit for imported shrimp and crayfish is currently at 1 ppb and is based on the method and the laboratory instrumentation originally available in the field laboratories. For the crabmeat products tested the detection (confirmation) limit was established at 0.5 ppb based on the method developed and published and the laboratory instrumentation available. This is the first reported test limit for crabmeat by ORA. We intend to maintain this level of testing for all imports of crabmeat for the immediate future.

You have correctly observed that we have begun testing crabmeat for CAP residues. The testing of crabmeat was initiated in response to state findings of CAP in imported crabmeat. Although we were not testing crabmeat prior to the notification by the state, our investigation of these state findings required field collection and testing to support any public health action. The test limit established for crabmeat permitted detection of CAP residues covering the range of levels reported by the state. We have confirmed the state findings through our independent investigation and we have and will continue to take appropriate action based on findings of CAP residues in crabmeat.

You have expressed a desire for greater communication among governments regulating CAP residues to facilitate a uniform, consistent regulatory and enforcement policy. We have been consistent in our communication with the states, foreign regulators, industry and the public that the sensitivity of FDA testing will ultimately conform to other foreign government limits for CAP at 0.3 ppb for all food products. Your members should anticipate a reduction in test levels to 0.3 ppb for all seafood by late March. The current 1.0 ppb test limits are not final and were established to permit immediate testing of a wide variety of imported food products.

We are sensitive to the adverse impacts to trade created by FDA regulatory strategies and enforcement actions. However it may not be possible to alert industry in advance of our regulatory activities in the manner you suggest especially when a public health threat has been identified. When possible, we will announce our intentions and communicate our actions to prompt the elimination of the sources of adulteration by the manufacturer and to support industry control and investigation of suppliers and manufacturers. It is not possible for the FDA to suspend its regulatory operations to provide advance notice to the affected industry and delay enforcement until industry has implemented effective controls.

Sincerely,

John M. Taylor, III
Associate Commissioner for
Regulatory Affairs